

9-1-2012

Randomized Comparison of Two Internet-Supported Natural Family Planning Methods (Final Efficacy Results)

Richard J. Fehring

Marquette University, richard.fehring@marquette.edu



RANDOMIZED COMPARISON OF TWO INTERNET SUPPORTED NATURAL FAMILY PLANNING METHODS (FINAL EFFICACY RESULTS)

2012 OPA Research Grantee Meeting

September 20-21

North Bethesda, MD

- Both Internet provided NFP methods were effective with correct use but the electronic hormonal monitoring method was statistically better with a typical use of only 7 unintended pregnancies per 100 women over 12 months of use compared with 19 with the traditional cervical mucus monitoring method.
- Satisfaction of using the hormonal method increased over time but motivation decreased, i.e., they had a desire to achieve a pregnancy.
- A high discontinuation rate contributed to the limitation of the study.
- However, this Internet based method of providing NFP with professional support is efficient and effective for select motivated couples.

RANDOMIZED COMPARISON OF TWO INTERNET SUPPORTED NATURAL FAMILY PLANNING METHODS (FINAL EFFICACY RESULTS)

2012 OPA Research Grantee Meeting

September 20-21

North Bethesda, MD

Marquette Research Team

- ▣ Richard Fehring, PhD, RN
- ▣ Mary Schneider, MSN, FNP
- ▣ Susana Crespo, BSN , RN
 - ▣ Kathy Raviele, MD
 - ▣ Jessica Pruszyński, PhD
- ▣ Teresa Roumonada, BA, RN
- ▣ Dana Rodriguez, MSN, PNP
 - ▣ Qiyan MU, BSN, RN

Overall Problem

- ▣ Only 0.1% of US women use modern methods of natural family planning.
- ▣ Women (and men) want safe, effective, easy to use, and convenient methods of family planning.
- ▣ Although NFP methods are free of side effects, they are often ineffective and complex to learn and use.

Way to Increase Use of NFP

- ▣ provide easy access
- ▣ to an effective but simplified NFP method that
- ▣ uses electronic hormonal fertility monitoring (EHFM),
- ▣ an internet based charting system,
- ▣ and online professional support.

Background

- ▣ In 2004, 54% of US households were connected to the Internet
- ▣ Each month approximately 2 million more people connect to the Internet
- ▣ Over 80% of Americans have accessed the Internet for health information
- ▣ Women access health information > than men
- ▣ Over 1 million Web sites with info on infertility

Types of Internet Studies

- ▣ Internet is #1 source of info for couples with infertility (Kahlor, and Machert, 2009).
- ▣ Characteristics of infertile couples
- ▣ Types of information sought
- ▣ Description of the experiences
- ▣ Assessed quality of information
- ▣ Few studies to determine efficacy

Intervention Studies

- ▣ Effect of providing med records online on empowerment (Porter & Bhattacharya, 2008).
- ▣ Effectiveness of a brief Web-based education and support system for female infertility patients (Cousineau, et. al., 2008).
- ▣ Only one study on the efficacy of teaching NFP/FA for achieving or avoiding pregnancy.

Marquette Online NFP

- ▣ Information on NFP and special circumstances
- ▣ Focused on teaching simple electronic hormonal fertility monitoring (EHFM) and/or cervical mucus monitoring (CMM)
- ▣ Online charting and interpretation
- ▣ Discussion rooms
- ▣ Consult nurse; physician; bio-ethicist



A NATURALLY HEALTHY APPROACH

[QUICK INSTRUCTIONS](#) | [NATURAL FAMILY PLANNING INFORMATION](#) | [ABOUT THE INSTITUTE FOR NATURAL FAMILY PLANNING](#) | [CONTACT US](#)

LEARN



INTRODUCTION TO NFP VIDEO

TRACK ONLINE



TRACK YOUR FERTILITY ONLINE

SHARE



NFP USER FORUM

REGISTERED NFP USERS

LOGIN

PASSWORD

SUBMIT

Not Registered? [Register here.](#)

Registration allows access to online forums, online charting and consultation with a Professional Nurse NFP Teacher, NFP Medical Consultant and Bioethicist.

Natural Family Planning

or as many simply call it "**NFP**", is a holistic and healthy way of planning a family. Essentially, it is the ability to monitor fertility and to modify behaviors according to the intention of either achieving or avoiding pregnancy.

The Marquette Model (MM) system of **NFP** brings 21st century technology to **NFP** by using the ClearBlue Easy Fertility Monitor, a device used at home which measures hormone levels in urine to estimate the beginning and end of the time of fertility in a woman's menstrual cycle. The information from the monitor can be used in conjunction with observations of cervical mucus, basal body temperature, or other biological indicators of fertility. The **MM** was developed by professional nurses and physicians at Marquette University in the late 1990s. A recent (2007) study published in the Journal of Obstetric, Gynecologic, and Neonatal Nursing demonstrated a 97-98% efficacy of the **MM** in avoiding pregnancy when taught by a qualified teacher and correctly applied.

Who can use the Marquette Model of NFP?

- Couples seeking to space pregnancies
- Couples struggling with infertility
- Breastfeeding women
- Peri-menopausal women
- Women with irregular cycles
- Women interested in health monitoring

How to get started learning and using the MM of NFP?

- Click on and view the Introduction to NFP video
- Click on and read the NFP Quick Instructions
- Click on, download, and read the NFP User Manual
- Click on, download, and start to chart your fertility indicators
- Better yet, register and track your fertility online.



TAKE THE NFP QUIZ



CHARTING AND MONITORING FERTILITY



AVOIDING OR ACHIEVING PREGNANCY



PROTOCOLS FOR SPECIAL CIRCUMSTANCES



BENEFITS OF USING NFP FOR MARRIAGE AND RELATIONSHIPS

Online Charting System

Marquette University Institute for Family Planning

Online Charting Tool

For Fertility Monitor and Cervical Mucus

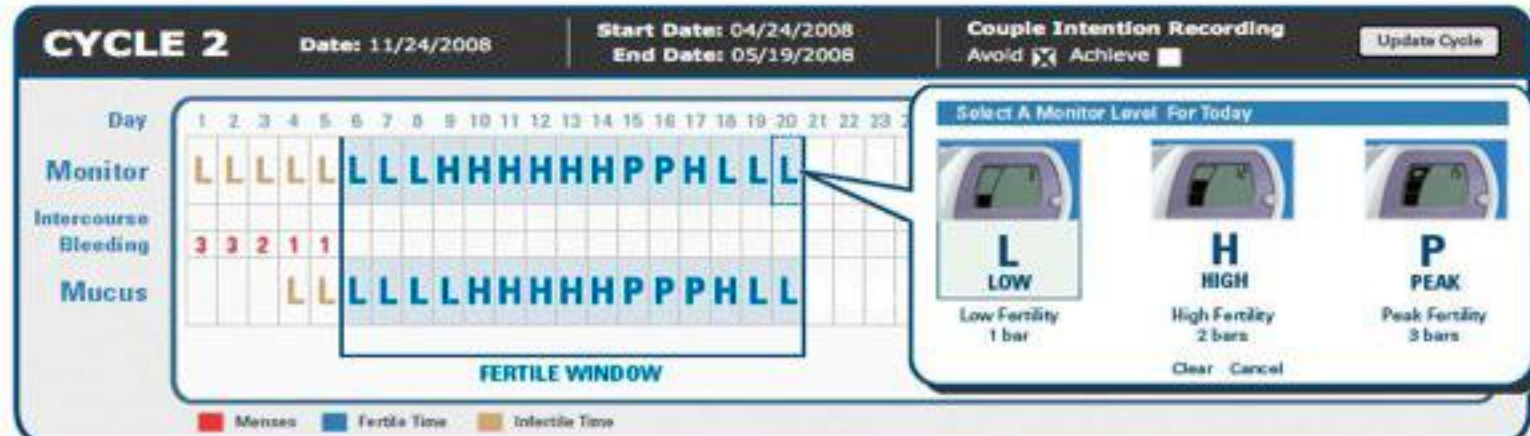
Username: nfp1001

Shortest of last 6 cycles: 27 days

Longest of last 6 cycles: 34 days

Earliest P in last 6 cycles: day 14

Latest P in last 6 cycles: day 21



Online Charting System

Marquette University Institute for Family Planning

Online Charting Tool

For Fertility Monitor and Cervical Mucus

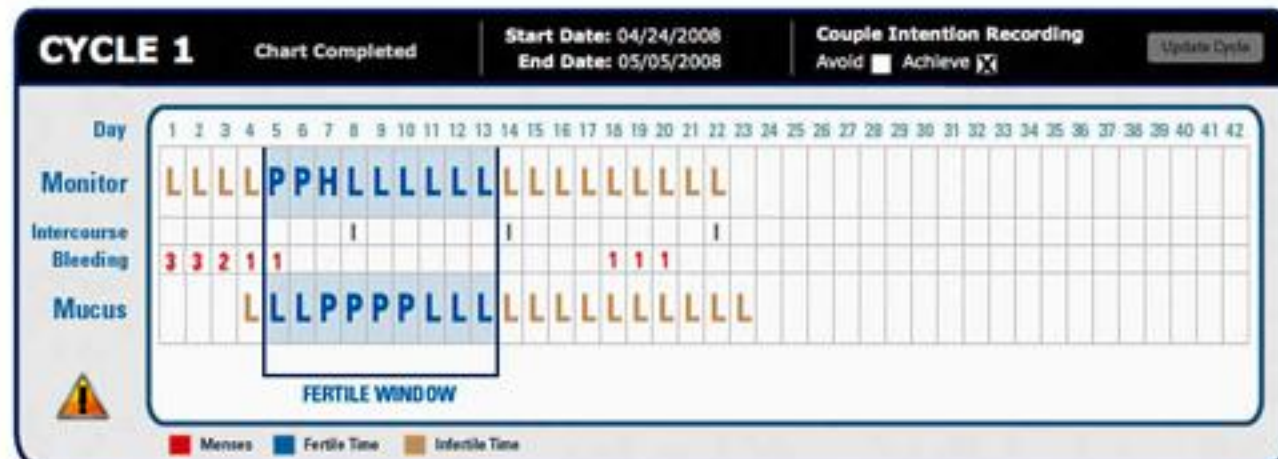
Username: nfp1001

Shortest of last 6 cycles: 27 days

Longest of last 6 cycles: 34 days

Earliest P in last 6 cycles: day 14

Latest P in last 6 cycles: day 21



Pilot Study

- ▣ 600 + participants using Web site to achieve or avoid pregnancy
- ▣ Outcomes = **Knowledge** of fertility; **Satisfaction** and ease of use at 1, 3 and 6 months of use
- ▣ **Unintended pregnancies** (automatic assessment)

Fehring, R, Schneider, M, & Raviele, K. (2011). Pilot Evaluation of an Internet-based Natural Family Planning Education and Service Program, *Journal of Obstetrics, Gynecology, and Neonatal Nursing*. 40(3):281-91.

Results – Participants (N=663)

	<u>Mean /SD</u>	<u>Range</u>
• Age	29.2 (SD=4.8)	20-42
• Yrs Married	4.7 (SD=5.1)	0-32
• Children	2.0 (SD=1.7)	0-10
• Weight	151 (SD=34)	90-315
• (N = 557) 80% College educated or more		
• (N = 578) 87% Catholic; (N = 53) 9% Protestant		
• (N = 452) 82% Euro-American; (N = 40) 7% Hispanic		
• (N = 317) 50% = Regular cycles; (N = 194) 31% Breastfeed		

Typical Pregnancy Rate

<u>Not Breastfed/N=142</u>	#	<u>Breast/N=159</u>	#
3 months = 0.991	1	0.974	2
6 months = 0.936	3	0.920	2
12 months = 0.912	1	0.880	1
Total:	5		5

Need for Study

- ▣ Although there have been studies to determine the knowledge base of an online hormonal contraceptive program there have been no (**comparative**) studies to determine the efficacy of internet-based instructions for NFP methods used to avoid pregnancy.
- ▣ Nor have there been (**comparative**) studies to determine the efficacy and satisfaction of using an online fertility charting system for NFP purposes.
- ▣ There are few comparison studies of NFP methods.

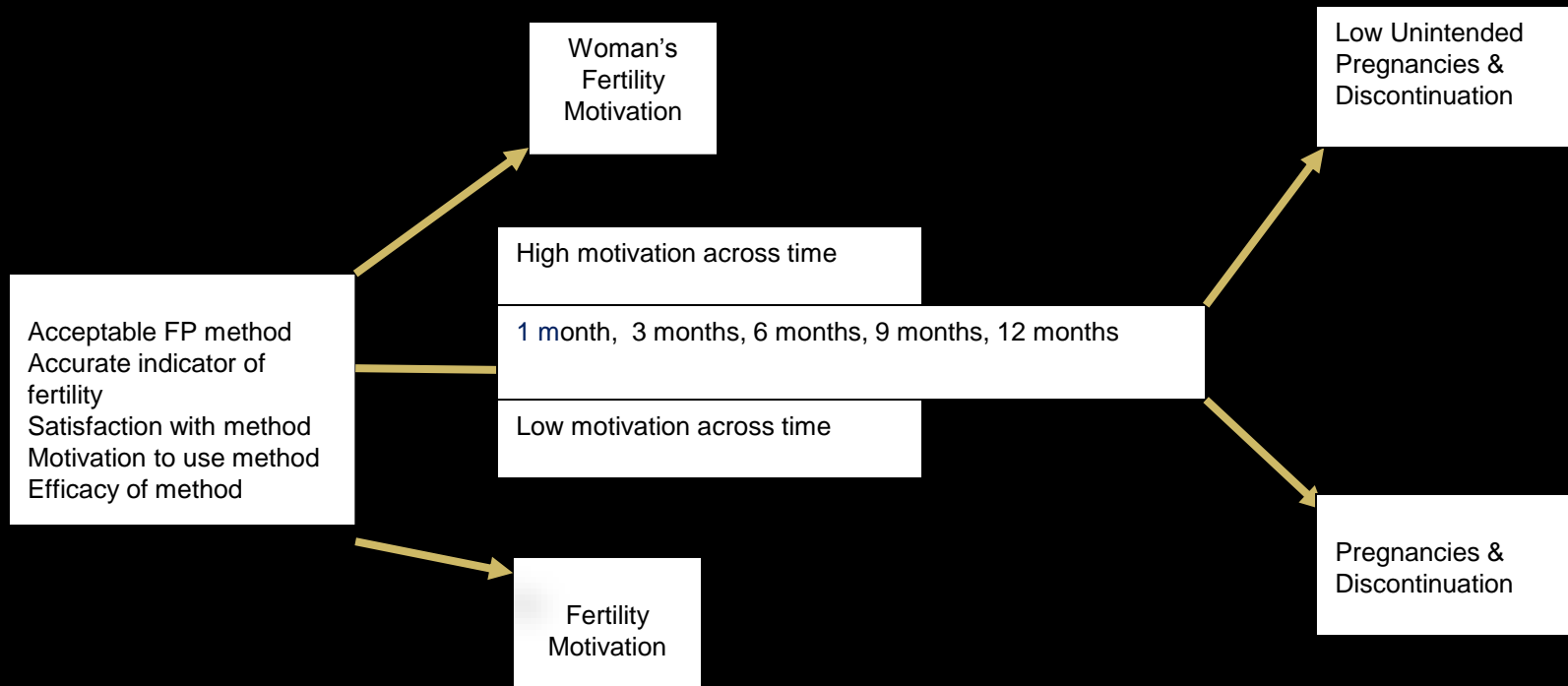
Comparative NFP Studies

- ▣ Wade ME, McCarthy P, Braunstein GD, et al. A randomized prospective study of the use-effectiveness of two methods of natural family planning. Am J Obstet Gynecol 1981;141:368-76. Comparing OM with STM.
- ▣ Fehring R, Schneider M, Barron ML, Raviele K. Cohort comparison of two fertility awareness methods of family planning. J Reprod Med 2009;54:165-170.

Mutual Motivation

- ▣ A key component in the use of NFP or any type of behavioral focused method of family planning is the motivation of both partners.
- ▣ If only one of the partners is committed to the method it will be difficult to use and the efficacy will most likely be lower.
- ▣ Mutual motivation has been recognized in the family planning and, in particular the NFP community, as essential for NFP efficacy.
- ▣ However, there have been no recent studies that have investigated this component for the use of NFP methods.

Mutual Motivation Model



Specific Aims

- ▣ To compare the **efficacy** in the use of two internet-supported methods of NFP (i.e., EHFM and CMM) in aiding couples **to avoid pregnancy**.
- ▣ To compare the **satisfaction and ease of use** in the use of two internet-supported methods of NFP (i.e., EHFM and CMM).
- ▣ To compare the **mutual motivation** in the use of two internet-supported methods of NFP (i.e., EHFM and CMM).

Methods



Design

- ▣ This is a 12-month (13 cycles) prospective randomized clinical efficacy trial of the EHFM plus fertility algorithm method of NFP in comparison with the CMM plus algorithm method of NFP.
- ▣ A minimum of 600 couples seeking to avoid pregnancy with a method of NFP and who have no known infertility problems are sought through an online NFP web site and randomized into either a EHFM group (N=300) or a CMM only group (N=300).

Female – Sample

- ▣ be between the age of 18 and 42
- ▣ be in a sexually active committed relationship with a man
- ▣ have a menstrual cycle range of 21-42 days
- ▣ have not used Depo (injectable) contraception for the past 6 months
- ▣ have not used oral or patch hormonal contraception for the past 3 months
- ▣ have not breast-fed baby for at least three months
- ▣ have no known fertility problems
- ▣ not be using medications that interfere with fertility
- ▣ not smoke cigarettes; and
- ▣ not be pregnant.

Male Partner Sample

- ▣ have no known fertility problems, and
- ▣ be between the ages of 18 and 50
- ▣ be in a sexually active committed relationship with his lone woman partner.

Study Procedure

- ▣ Online 12 minute intro slide show
- ▣ Online consent
- ▣ Automatically randomized
- ▣ Send monitor
- ▣ Online charting
- ▣ Automatic reminder to complete measures, 1, 3, 6, 12 months
- ▣ Online pregnancy evaluation

Outcome Measures

- ▣ Unintended pregnancy – assessed by pregnancy evaluation tool and urine pregnancy test.
- ▣ Ease of Use/Satisfaction of method – measured by a 10 item acceptability scale (scored 1-7).
- ▣ Combined Mutual Motivation Score (0-40)
 - How hard are you trying to avoid pregnancy?
 - How much do you want to avoid pregnancy?

Results

Descriptive Statistics

	<u>Monitor (N=197)</u>	<u>Mucus (N=161)</u>
Mean age female	29.7 (SD=5.4)	30.6 (SD=5.3)
Mean age male	31.5 (SD=6.1)	32.5 (SD=6.2)
Mean years married	5.8 (SD=5.0)	6.3 (SD=5.1)
Mean # living children	1.8 (SD=1.9)	2.1 (SD=1.9)
Mean weight female	146.9 (SD=30.1)	153.6 (SD=37.1)
Mean height female	65.3 (SD=2.8)	65.0 (SD=2.6)
% Ethnicity	77% White/7% Hispanic	84% White/5% Hispanic
% Religion	76% Catholic/18% Prot	81% Catholic/14% Prot

** There were no significant differences between the two study groups on demographic variables.*

Gross Pregnancy Rate

Monitor (N = 197)

Pregnancies = **32**

Mucus (N = 161)

Pregnancies = **32**

3 months:	10	94.6	.02	14	90.1	.03
6 months:	8	89.0	.03	8	82.7	.03
9 months:	8	82.7	.03	6	76.3	.04
12 months:	6	76.3	.04	4	71.8	.04

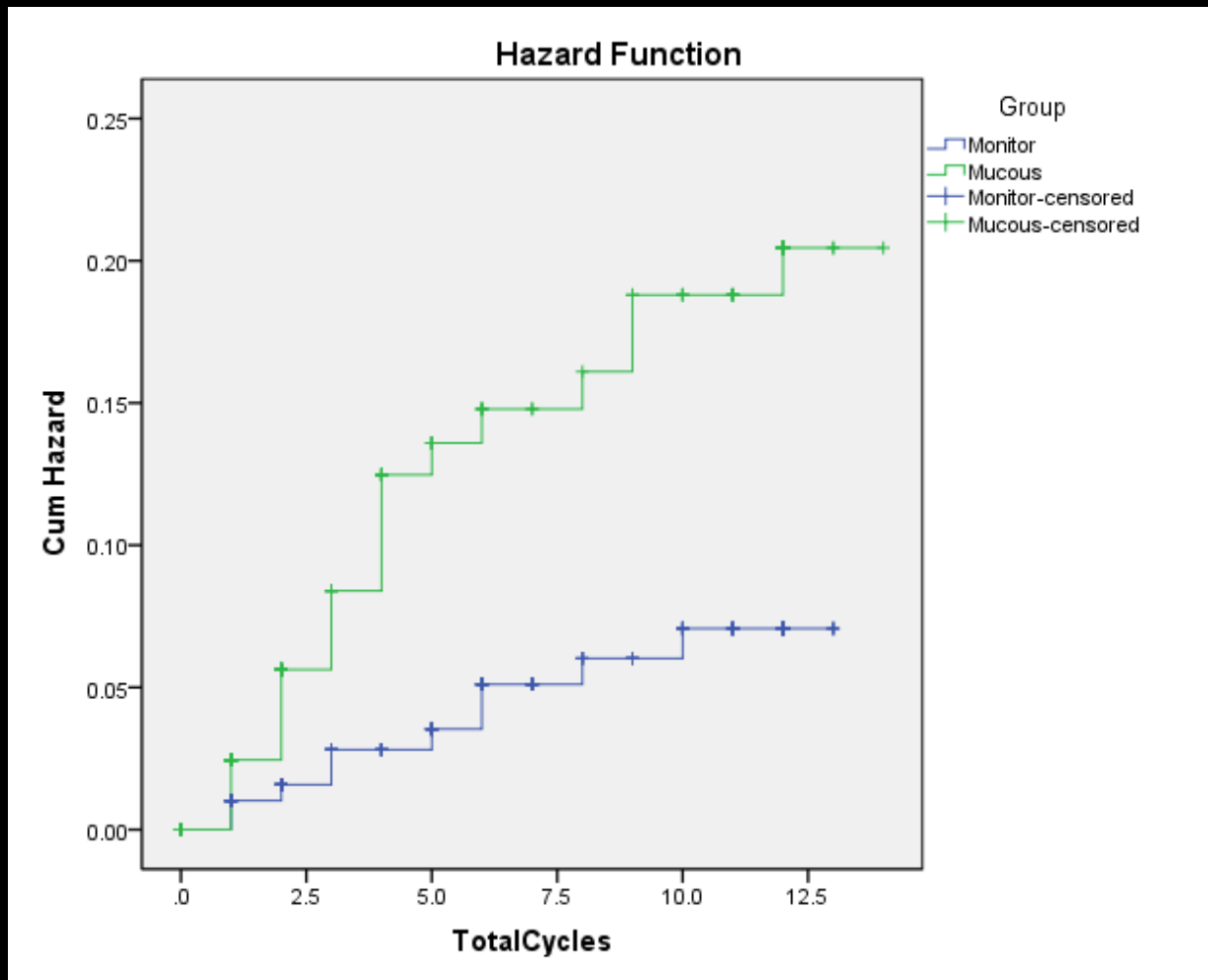
Perfect Use Efficacy

- ▣ The *perfect use* and *total* unintended pregnancy rates of the two study groups are based upon **1,126 cycles** of correct use and **2,780 total cycles** of use.
- ▣ The *perfect use* pregnancy rate per 100 women over 12 months of use in the EHFMM group was **0** for the monitor group and **2.7** for the mucus group.
- ▣ There were no differences between the two groups in perfect use pregnancy rates.

Net Unintended Pregnancy Rates

<u>CORRECT USE</u>			<u>TYPICAL USE</u>		
MONITOR		MUCUS	MONITOR		MUCUS
N = 197		N=161	N = 197		N=161
Pregnancies = 0		= 3	Pregnancies = 10		= 21
3 cycles:	0.00	0.97	3 cycles:	0.97	0.92
6 cycles:	0.00	0.97	6 cycles:	0.95	0.86
9 cycles:	0.00	0.97	9 cycles:	0.94	0.83
12 cycles:	0.00	0.97	12 cycles:	0.93	0.81
Std Error:	.00	.016	Std Error:	.022	.038

Hazard Ratios



Log rank statistic

<i>Group</i>	<i>Kaplan- Meier estimate</i>	<i>St. error</i>	<i>Log rank T.S.</i>	<i>p-value</i>
Monitor	0.932	0.021	8.76	0.0031
Mucus	0.815	0.038		

Ease of use/Satisfaction By Month

	<u>Monitor</u>		<u>Mucus</u>			
	N	Mean/SD	N	Mean/SD	t	Sig.
1	173	57.00 8.62	128	54.17 9.63	2.57	.01
3	153	57.58 9.52	107	55.28 10.9	1.50	.13
6	120	59.81 7.16	87	56.46 11.09	2.24	.03

Motivation by Month

		Monitor				Mucus			
	N	Mean/SD		N	Mean/SD		t	Sig.	
1	162	36.06	7.92	108	37.11	6.45	1.15	.24	
6	128	34.62	11.9	84	37.21	4.33	2.83	.05	
12	82	32.86	13.1	62	37.24	2.58	2.87	.02	

Discussion I

▣ *Efficacy of Methods*

- Very effective correct use for both method
- Monitor has lower unintended pregnancy rate

▣ *Satisfaction/Ease of use*

- Trend towards greater satisfaction with monitor
- Similar to past studies showing increase over time

▣ *Motivation*

- Greater motivation to avoid among mucus group
- Some sought monitor to achieve pregnancy

Discussion II: Implications

▣ *Practice Implications:*

- Effective online method
- Efficient way to provide health consultation

▣ *Policy Implications:*

- Title X Clinics or Region could offer online NFP
- Diocesan programs could offer online NFP

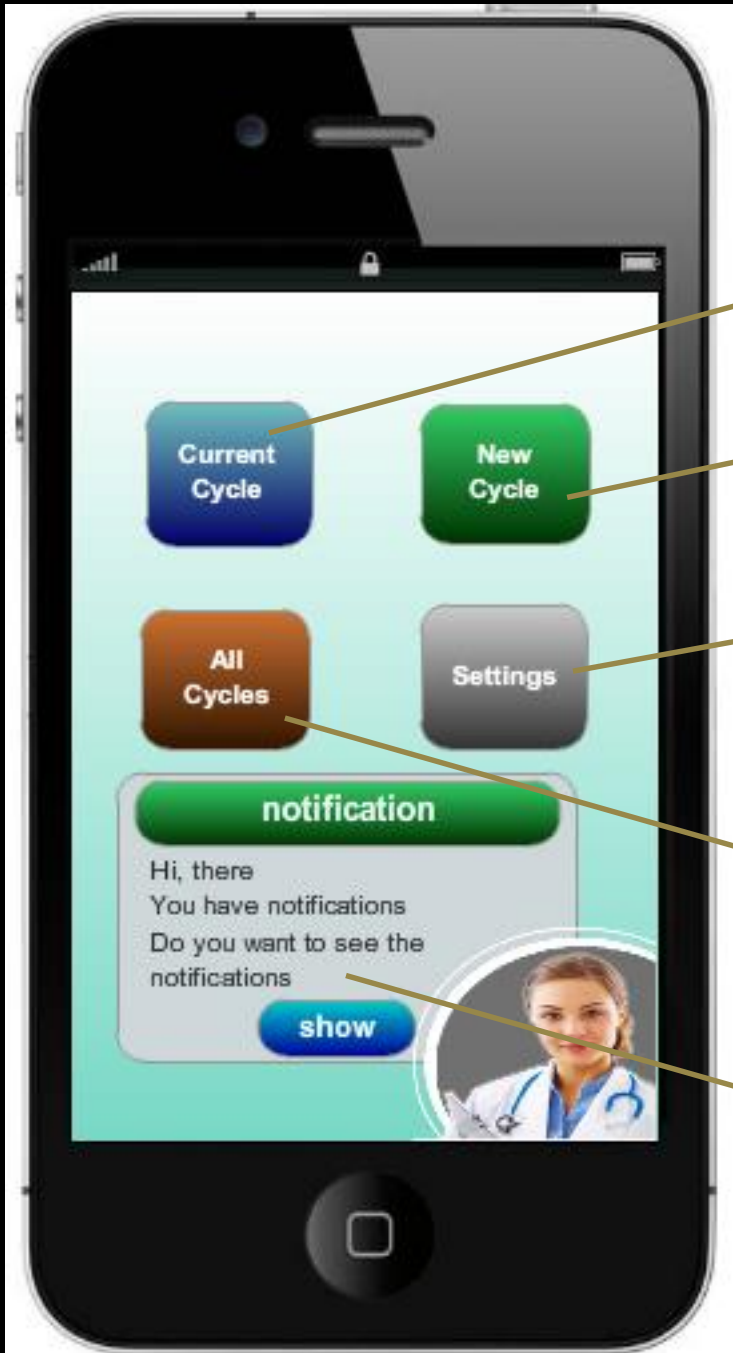
▣ *Research Implications:*

- Enroll only participants who are new to NFP
- Don't allow retrospective charting
- Use similar system to determine efficacy to achieve

Future Studies

- ▣ Analyze motivation and other factors, e.g., age
- ▣ Analyze cycle parameter data
- ▣ Analyze qualitative responses
- ▣ Analyze all pregnancies and intercourse patterns (? – count of 2 days past second peak?)
- ▣ Determine efficacy in use of fertility monitoring app.

Home Screen



View current
cycle

Create new cycle

Settings:
Changing user
name, or other
info

View All Cycles

Notification area

Current Cycle

The screenshot shows a mobile application interface for tracking a menstrual cycle. The interface is divided into several sections:

- Calendar area:** A 7x6 grid of dates from 1 to 42. The current date, 11, is highlighted in blue.
- Current date status:** A bar displaying the date 02-22-2012.
- Monitoring section:** A table with four rows: MONITOR, MUCUS, INTERCOURSE, and SYMPTOMS. Each row has a dropdown menu and a status field.
- Update button:** A green button labeled UPDATE.

MONITOR	L	LH	L
MUCUS	2	Temperature	
INTERCOURSE		BLEEDING	
SYMPTOMS			

UPDATE

Calendar area

Showing
current date

Current date
status

Update
button

Conclusion

- Both the online EHFM and CMM methods are effective with correct use but EHFM method has better overall efficacy.
- Furthermore, although the ease of use/satisfaction of the EHFM method increase over time, the motivation to avoid decreased over time.
- High rate of discontinuation.